

Remarks

In the Claims

According to the Response filed on April 9, 2010, claims 26, 30, **35**, 37, 48, 49, 53 and 60 were amended; and claims 28, 43, 51 and 66 were canceled. Therefore, claims 26, 27, 29-42, 44-50, 52-65 and **67-71** are currently pending in the application. The Examiner is requested to acknowledge the status of the claims as summarized above, as it differs from the Office Action mailed on July 16, 2010.

As discussed in greater detail below, Applicant has amended claims 26 and 49. Entry of the amendments is respectfully requested, as they place the claims in condition for allowance. No new matter has been added.

Claim Rejections – 35 USC 112

Alleged new matter

The Office Action rejected claims 26-27, 29-42, 44-50 and 52-65 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action questions whether there is word-for-word or inherent support in the specification for reciting in claims 26 and 49 that the container spiking assembly controller controls the movement of at least a portion of the container spiking assembly, and without reciting that the port assembly (e.g., spike receptacle) and container receptacle (e.g. vial assembly) are positioned and locked in place.

Applicant disagrees with the Examiner's position. However, in an effort to advance prosecution of the application, amendments have been made to claims 26 and 49 that, if entered, should place the claims in condition for allowance. Claim 26 has been amended to recite that the container spiking assembly comprises a movable member adapted to move the container receptacle toward the port assembly. Claim 49 has been amended to recite a positioning means for moving the container receptacle toward the port assembly. Furthermore, in both claims 26 and 49, coupling of the container receptacle with the port assembly is configured to occur while the port assembly is immobilized relative to the container receptacle.

. The specification provides an example of the claimed apparatus by describing the structure of a vial spike assembly that can advance a vial assembly toward a spike receptacle.

This description is sufficient to support the claims as written. “The written description requirement does not require the applicant to ‘describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.’” Union Oil Co. of California, v. Atlantic Richfield Co., 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) (*quoting* In re Gosteli, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)).

As stated in paragraph 0098 of the specification, a process controller 120 can control a vial spike assembly 406 and pneumatic control assembly 410. Furthermore, as stated in paragraph 0100, the pneumatic control assembly 410 is associated with a master module 512. The module 512 includes a CPU board, among other things, and is used to control the pressures in a bladder in the vial spike assembly 406. (*see, e.g.*, paragraph 0102). An I/O board of the module controls various sensors in the vial spike assembly 406 (*id.*). In an exemplary embodiment, the vial spike assembly 406 includes both stationary and movable components: a stationary cylinder 912, and movable piston 904 operating within the cylinder, and connected to a movable bladder plate 906 by a movable shaft 920. A bladder 918 can control movement of the piston 904 within the cylinder 912 by operating on the bladder plate 906 (*see, e.g.*, paragraph 0129).

As shown above, there is explicit support for a container spiking assembly controller that controls one or more movable components of a container spiking assembly. In the example described, the movable components can at least include a piston, a bladder plate, a shaft, or a bladder. Thus, the specification provides adequate support for the claims as written.

The Office Action also expressed a concern that the specification indicates that the bladder 918 can be inflated once the vial assembly 200 and spike receptacle 310 are positioned and locked in place. In this application, the container receptacle (e.g., vial assembly) is configured to move toward the port assembly (e.g., spike receptacle) in order to result in a coupling between the two. It is the Applicant’s position that this feature is inherent in the claims as written. Nevertheless, the proposed amendments to claims 26 and 49 now recite that the container receptacle is configured to couple with the port assembly while the port assembly is immobilized relative to the container receptacle. Support for the amendment is provided at least, for example, in Figs. 9E and 9F. In Fig. 9E, the spike receptacle housing section 344 is in a

position to receive the vial receptacle 206, and in Fig. 9F, the vial receptacle 206 has been advanced into the housing 344, under the influence of the movable components (e.g., 918, 906, 920, 904) of the vial spike assembly 406.

Applicant therefore believes that the amendments satisfy the concerns raised by the Office Action. Because the amendments place the claims in condition for allowance, Applicant respectfully requests withdrawal of the claim rejections under 35 U.S.C. §112, entry of the amendments, and allowance of the claims.

**Conclusion**

For the foregoing reasons all of the claims of the present invention are patentable over the art of record. It is believed that all of the claim rejections have been addressed and that the application is now in condition for allowance. Reconsideration of the claims and issuance of a notice of allowance are respectfully requested. If any matter arises for which an interview may expedite issuance of a notice of allowance, the Examiner is requested to call the undersigned at the telephone number given below.

This response is being filed within two months from the mailing date of the Office Action, and no extension fee is believed to be currently due. However, if any fee is required for timely consideration of this application, Applicant requests that it be charged to Deposit Account No. 50-4383.

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Respectfully submitted,

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